REMARKS

I. Status of the Claims

Claims 1-12 are pending in the present application. Claims 13-16 have been withdrawn from consideration as a result of Applicants election, with traverse, of Group I claims in response to the restriction requirement dated October 15, 2002.

Applicants maintain their traversal of this restriction requirement. Reconsideration and withdrawal of this restriction requirement is respectfully requested for the reasons set forth in the response submitted October 25, 2002 as supplemented below. Should this restriction requirement be maintained, Applicants reserve their right to file a petition to the Commissioner under 37 C.F.R. §§1.144 and 1.181 at any time until after final action or allowance of the elected claims to review the propriety of this requirement.

With respect to restriction of Group I claims from Group II-IV claims, Applicants have pointed out that the claims of groups II-IV are drawn to a kit that is specifically designed to perform the methods of claim group I. However, the Examiner has maintained that restriction is proper because "comprising" language used in the kit claims means that additional components can be added to perform methods beyond those of Group I claims. While it may be possible to add components to the claimed kits to perform other methods, such a possibility is irrelevant because it does not create any additional search or examination burden on the applicant. The critical question for examination purposes is whether a kit with the recited components (not theoretical additional components) is patentable over the prior art. Certainly Applicants cannot rely on the possibility of adding components to the claimed kits to assert patentability over the prior art.

With respect to claim groups II-IV, the examiner has maintained restriction on the basis that the nucleotide sequences recited in each group are unrelated. Applicants disagree. The specification describes the relationship of the alleles from which these nucleotide sequences are derived with respect to antibiotic tolerance .

While Applicants can sympathize with the search burden imposed by a multitude of sequences presented in other applications, this is certainly not the case in the present application. The present claims include a total of six primer sequences of 20 nucleotides each. Examination of all six primer sequences does not represent an undue search burden warranting restriction.

II. The Rejections

A. The rejection of the claims under 35 U.S.C. §112, second paragraph

At page 3 of the Office Action, the Examiner has rejected claims 1-8 under 35 U.S.C. §112, second paragraph based on the assertion that the phrase "likely to be tolerant" renders the claims indefinite. Applicants respectfully traverse this rejection for the reasons provided below.

The present invention is based on the association of particular allelic combinations with antibiotic tolerance. As described in the specification, this association is imperfect and does not represent an exact correspondence (*See*, in particular, page 14, lines 1-9). Due to the imperfect nature of this association, it is not possible to describe it with complete precision. Therefore Applicants have used the phrase "likely to be tolerant" to describe this association as precisely as possible.

Courts have recognized that claim language can only be as precise as the subject matter permits and have ruled that language similar to that used here complies with the definiteness requirement. *Verve, LLC v. Crane Cams, Inc.*, Slip No. 01-1417 (Fed. Cir. Nov. 14, 2002); *Andrew Corp. v. Gabriel Elecs. Inc.*, 6 USPQ2d 2010, 2013 (Fed. Cir. 1988); *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 1 USPQ2d 1081, 1088 (Fed. Cir. 1986); *Hybridtech, Inc. v. Monoclonal Antibodies, Inc.* 231 USPQ 81, 94 (Fed. Cir. 1986); *Shatterproof Glass Corp. v. Libbey Owens Ford Co.*, 225 USPQ 634, 641 (Fed. Cir. 1985). Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

B. The rejection of the claims under 35 U.S.C. §101/112

At pages 3-5 of the Office Action, the Examiner has rejected claims 1-12 under 35 U.S.C. §101 asserting that the claimed invention lacks patentable utility. Applicants respectfully traverse this rejection for the reasons provided below.

In making this rejection, the Examiner erroneously refers to "[t]he claimed nucleic acid and/or protein compounds". Applicants have claimed methods, not nucleic acid or protein compositions. Assertions of nonutility of these compositions do not support rejection of the claimed methods.

The claimed methods can be used to determine whether a particular bacteria is likely to be antibiotic tolerant. As noted in the paragraph bridging pages 9 and 10 of the specification, these methods can be used to help determine whether a subject suffering from a bacterial infection can be effectively treated with antibiotics. Knowing whether a bacteria is likely to be antibiotic tolerant provides useful information which can be taken into account when considering treatment options. To be useful in this regard, it is not necessary for the method to provide a definitive conclusion with regard to the presence or absence of antibiotic tolerant bacteria.

The utility of the claimed methods for determining whether a bacteria is likely to be antibiotic tolerant represents a specific, substantial and credible utility that satisfies the requirements of patentability. Reconsideration and withdrawal of this rejection, as well as the enablement rejection made under 35 U.S.C. §112 based on the same assertions, is respectfully requested.

C. The rejection of the claims under 35 U.S.C. §102

At pages 6-7 of the Office Action, the Examiner has rejected claims 1-3 and 8 under 35 U.S.C. §102(b) asserting that the claimed invention is anticipated by Novak *et al.* (international patent application pub. No. WO 99/57281 published November 11, 1999). Applicants respectfully traverse this rejection for the reasons provided below.

Novak provides background information regarding the vex2, pep27 and vncs genes and describes loss of function mutants, but it does not disclose the present invention. Contrary to the Examiner's assertions, Novak does not disclose the identity of the type 4 or R6 diagnostic alleles of the vex2 and pep27 genes taught by the present invention. Since these alleles are not

disclosed, Novak clearly cannot describe the association between these particular allelic combinations and antibiotic tolerance on which the present claims are based. Should this rejection be maintained, Applicants would ask the Examiner to more particularly point out the text in Novak which discloses these alleles and their importance.

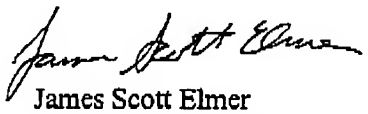
In view of the remarks above, reconsideration and withdrawal of this rejection is respectfully requested.

V. Conclusion

In view of the remarks above, it is believed that the Examiner may properly withdraw the rejections of the claims under 35 U.S.C. §101, §102(b), and §112, first and second paragraphs.

Having now fully responded to the Examiner's rejection of the claims, Applicants respectfully submit that the present application is in condition for allowance and earnestly solicit early notice of such favorable action. No fee is believed to be required for consideration of this submission. If applicants are incorrect and a fee is required the Commissioner is hereby authorized to charge such fee to Deposit Account No. 501968.

Respectfully submitted,



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